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10/508,894

09/22/2004

Ajita Bhat

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10/25/2006

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EXAMINER

TUCKER, ZACHARY C

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/508,894

Applicant(s)

BHAT ET AL.

Examiner

Zachary C. Tucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-91 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 49-91 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>22Sep04, 3May05</u> . | 6) <input type="checkbox"/> Other: ____. |

Lack of Unity of Invention

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 49-72, 89 and 90, drawn to chemical compounds of the Formula (I), and a pharmaceutical composition comprising the same.

Group II, claims 73-88, drawn to a method for the prevention or treatment of an LXR mediated disease or condition, comprising administering a therapeutically effective amount of a chemical compound of the Formula I-A

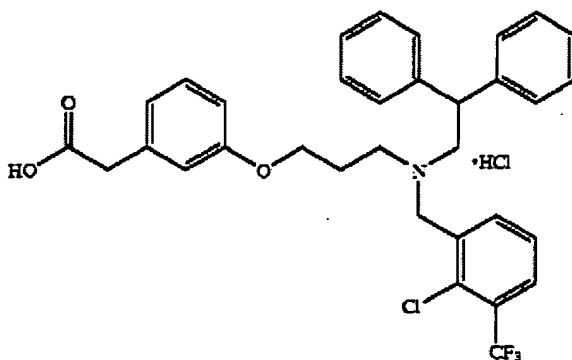
Group III, claim 91 drawn to a group of nineteen chemical compounds, which are taught as having utility as intermediates in the production of compounds according to compounds of the formulae I and I-A (page 50, lines 15+ of the instant specification).

The inventions listed as Groups I, II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The element common to Group I and Group II, which element is the compounds according to Formulae I and I-A, is known from the prior art. Thus, because the feature shared by both Groups is not a contribution over the prior art, the two Groups do not share a special technical feature as provided for in the PCT rules.

To wit: United States Patent Application Publication Number 2004/0072868 (Collins et al) discloses several compounds embraced by Formulae I and I-A. In Example 18, synthesis of the hydrochloride salt of 2-(3-{3-[[2-chloro-3-(trifluoromethyl)benzyl](2,2-

diphenylethyl)amino]propoxy)-phenyl)acetic acid is described. The compound has the structure represented by the diagram shown here:



The compound is embraced by instant claim 1 wherein X is $-\text{COOR}^{10}$, where R^{10} is H and $p=1$; $k=0$; Z is CH; Y is -O-; W^1 is aryl (phenyl), W^2 and W^3 are both H and $m=1$; $t=0$; Q is aryl (phenyl), where $q=1$.

Applicants may opine that since no finding of lack of unity of invention was set forth in the International Search Report (which, incidentally, was prepared by the undersigned), no such finding should be made here. The examiner would answer such an argument by pointing out that the patent application publication cited in the preceding, which discloses compounds according to Group I as set forth above, was not published until *after* the International Search Report was prepared and furthermore is prior art under 35 U.S.C. 102(e) only, for which there is no equivalent provision in PCT Rules 33(2) and 33(3) (which are the rules establishing what constitutes prior which will render a claimed invention unpatentable in the context of the Patent Cooperation Treaty).

Group III, intermediate compounds, is not overlapping or commensurate in scope with Group I or II, and does not require any of the particulars of either Group I or II. The

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intermediate compounds furthermore are not specially adapted solely for the manufacture of Group I compounds.

This Finding is Further Set Forth as Follows:

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Whichever Group as set forth hereinabove is elected, applicants are required to elect a single disclosed species from that Group. If Group I is elected, then the election of species requirement pertains to election of a single chemical compound of Formula I. If Group II is elected, then the election of species requirement pertains to the election of a single chemical compound with which the method is practiced. If Group III is elected, the election of species requirement pertains to election of one of the nineteen compounds named in claim 91.

Formulae I and I-A, and claim 91 are generic to a plurality of patentably distinct compounds. For example, the variable "X" may be an acyclic moiety, a heterocyclic linker moiety, or absent. Variable "Z" may be a carbon or nitrogen atom, providing for a phenyl or pyridyl ring; either alternative provides for a variant which does render other obvious. Variable "W¹" will have any number of carbocyclic or heterocyclic identities, further providing for species which are patentably distinct over one another. The totality of all of the individually variable elements of Formulae I and I-A creates a very large genus of compounds not all of which are seen as being chemically equivalent or related.

Claim 91 compounds are not seen as being related chemically, at least for the reason that some are sulfonamides, some are silyl compounds, some are amines and some are heterocycles.

Thus, a requirement for applicants to elect a single disclosed species of the invention is proper. Search and examination of the elected claims will proceed bearing in mind applicants' election of species, and the search will be broadened as necessary, if prior art is not found. MPEP 803.02 explains "Markush practice" with respect to the election of species requirement.

Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, *and a listing of all claims readable thereon*, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. It is requested that applicants kindly identify exactly where in claim 68 the elected species may be found, should the species elected be one of the compounds specified in that claim.

Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

This Finding is Subject to the Following Conditions:

The examiner has required restriction between compounds and method of use claims. Where applicant elects claims directed to compounds, and a compound claim is subsequently found allowable, withdrawn method of use claims that depend from or otherwise include all the limitations of the allowable compound claim will be rejoined in accordance with the provisions of MPEP § 821.04. Method of use claims that depend from or otherwise include all the limitations of the patentable compound will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the compound claims and the rejoined method of use claims will be withdrawn, and the rejoined method of use claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected compound claim is found allowable, an otherwise proper restriction requirement between compound claims and method of use claims may be maintained. Withdrawn method of use claims that are not commensurate in scope with an allowed compound claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the method of use claims should be amended during prosecution either to maintain dependency on the compound claims or to otherwise include the limitations of the compound claims. Failure to do so may result in a loss of the right to rejoinder. Further,

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note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Comments

As a courtesy, so that applicants may correct some deficiencies in the claim set prior to the first action on the merits, the examiner offers these observations:


In claim 49, there does not appear to be a definition for the variables "Het" and "Ar." Also in claim 49, in the definition for "W¹," the claim recites "W¹ is selected from C₁-C₆ alkyl, C₃-C₈ cycloalkyl, aryl, Het, wherein said C₁-C₈ alkyl, C₃-C₈ cycloalkyl, Ar and Het are optionally..." In this recitation, there appears no antecedent basis for the "said... Ar" phraseology.

Conclusion

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Monday to Friday from 5:45am to 2:15pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600



Zachary C. Tucker
Primary Examiner
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